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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/063,227	04/20/1998	JESUS W. CASAS-BEJAR	P-7109	4100

27581 7590 09/05/2003

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EXAMINER	
THISSELL, JEREMY	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 09/05/2003

35

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

Office Action Summary	Application No.	Applicant(s)	
	09/063,227	SCHROEDER ET AL.	
	Examiner	Art Unit	
	Jeremy T. Thissell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-19,24,27,29,33,34,36-39,41,43 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-19,24,27,29,33,34,36-39,41,43 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *35* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 August 2003 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39, and 41 rejected under 35 U.S.C. 102(b) as being anticipated by Helmus et al (US 5,447,724).

Helmus teaches all the claimed subject matter including an implantable medical device (col. 3, line 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 55) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46), wherein the drug makes up 2% by weight of the material (col. 7, lines 57-62).

Note that col. 7, lines 57-62 indeed specify the OUTER layer, not the reservoir layer. In col. 7, lines 57-62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release effect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir layer. Since this teaches that the agent in the outer layer can be the same as in the inner layer, Helmus' teaching of the reservoir agent being a steroid (col. 6, line 55) is interpreted as referring to physiologically active agents in BOTH the reservoir and outer layer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724).

Helmus teaches all the claimed subject matter except for the slightly lower concentrations in claims 37 and 43. Helmus teaches 2% of the material is the drug, whereas the claims call for a maximum of 1%. In a tissue-contacting wall of a catheter, the amounts of a drug that are needed to achieve a desired release rate vary somewhat

based on the specific material that the drug is being mixed into, and also how the catheter was formed (i.e. extrusion process, etc.). Therefore, the examiner takes the position that it would have been obvious to one of ordinary skill in the art to vary the weight percentage of a drug such a small amount in order to achieve a desired release rate depending on the polymer being used and the manufacturing process (temperature, curing, etc) used to make the catheter.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chait (US 5,727,555) in view of Helmus et al (US 5,447,724).

Chait teaches a catheter having an external fitting coupled to the proximal end, and helical coils as claimed. However, Chait lacks a layer with anti-inflammatory agent in it. Helmus teaches an elongate body-inserted member with an anti-inflammatory agent imbedded in the tissue-contacting surface as discussed supra. It would have been obvious to one having ordinary skill in the art to form the catheter of Chait with the layered structure of Helmus in order to reduce inflammation in the treatment area, since formation of catheters with layers and with drug-saturated layers is well known in the art of catheters.

Claims 17-19, 38, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al (US 5,609,629).

Helmus teaches all the claimed subject matter except for the steroid being a glucocorticosteroid such as dexamethasone. Fearnot teaches the use of

dexamethasone in a drug embedded outer layer of a catheter. It would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 54-55) since dexamethasone is a well-known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

Response to Arguments

Applicant's arguments filed 18 August 2003 have been fully considered but they are not persuasive.

Applicant argued that Helmus does not teach a tissue-contacting layer with a drug intimately mixed in it. Applicant argues that the outer layer is porous and thus drugs within the pores are not "intimately mixed" in the material. However, the material of the outer layer does have a drug intimately mixed therein (col. 4, lines 23-24). It has pores to allow MORE drug from the reservoir to pass therethrough, but Helmus teaches that size of the pores left behind are intentionally made small enough to prevent tissue ingrowth.

Applicant also argued that the high temperature manufacturing processes like thermal extrusion would preclude the desired composition of drug/polymer. However, thermal extrusion is not the only process by which Helmus' invention can be made. Col. 4, lines 16-19 teaches simple coating the layer on by a form of dipping the catheter (see also col. 9, lines 4-49). Each of the passages in col. 4, lines 16-19, 23-24, and col. 9,

lines 4-49 teach that the surface layer material is a "mixture" of the polymer and the elutable agent.

Applicant's have attempted to claim a means for modulating degradation or tissue encapsulation of a catheter. The means being a surface layer having a physiologically active agent mixed therein. Applicant's specification discusses the principles behind the invention. Indwelling catheters are subject to encapsulation or degradation due to the body's natural immune response to a foreign object. Applicant feels that they have realized the effectiveness of anti-inflammatory agents in preventing encapsulation or degradation of the catheter, because they reduce the body's immune response. Firstly, the prior art teaches the same means as claimed by applicant. Secondly, the prior art, specifically Helmus, teaches that the agent (steroids) may be used "to prevent excessive fibrous tissue formation." (Col. 6, lines 56-57) Applicant explains in its own specification that this fibrous tissue formation is what causes encapsulation. (Specification, page 6, lines 23-24). Helmus also teaches that the agent may be one for preventing calcification (degradation) of the biomedical materials (Helmus: col. 6, line 68—col. 7, line 3).

Further, regardless of what Helmus uses the agents for, the mere fact that the device has the same structure (including the agent) anticipates the instant claims. See MPEP 2112.01, reproduced below for convenience.

> MPEP 2112.01 Composition, Product, and Apparatus Claims
> **PRODUCT AND APPARATUS CLAIMS — WHEN THE STRUCTURE RECITED IN THE REFERENCE IS SUBSTANTIALLY IDENTICAL TO THAT OF THE CLAIMS, CLAIMED PROPERTIES OR FUNCTIONS ARE PRESUMED TO BE INHERENT**
> Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes,

> a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).
>
> See also Northam Warren Corp. v. D. F. Newfield Co., 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) (A patent to a pencil for cleaning fingernails was held invalid because a pencil of the same structure for writing was found in the prior art.).

Therefore, even if Helmus did not teach that the agent can be one for inhibiting growth of fibrous tissue or calcification of the device materials, it would still anticipate the present claims because Helmus teaches the same structure (a catheter with the claimed agent).

Finally, Applicant argued that it would not have been obvious to alter the amount of drug as discussed above (i.e. obvious to make the wt% 1% instead of the 2% taught by Helmus). In the telephone interview, Applicant's representative argued that the reason Applicant has claimed such a low concentration is that some drugs work with lower concentrations than others, which is why Applicant also discloses concentrations up to 5 wt %. Applicant claims that they use lower concentrations because they are using the agents for different purposes than their predecessors.

The examiner does not find this argument persuasive for three reasons.

First, Applicant shows no criticality for having such a low concentration. It appears that the device will work with concentrations much greater (see discussion of 5 wt % above). In fact, Applicant's own specification, page 11, line 28—page 12, line 4 teaches *inter alia* that, "The anti-inflammatory agent can be used in any amount that produces the desired response without detrimental effects, such as cytotoxic effects or the suppression of the immune response." These discussed detrimental effects are

biological, including cell damage and over-suppressing the immune response. As such, there is no mention of detrimental effects to the device due to higher concentrations.

Second, Helmus teaches a general "minor" amount of "about 2%," but says so without specifically teaching exact amounts for each different agent disclosed. This is a "loose" teaching of a ball-park figure, rather than a hard and fast amount that must be adhered to.

Third, Helmus teaches that the agent, such as the disclosed steroids, can be one for preventing growth of fibrous tissue or damage to the medical device, just the same as applicant. Therefore, Applicant's argument that their device is used for a different purpose is not valid.

The Examiner takes the position that one of ordinary skill in the art would, in view of the lack of criticality, lack of harmful effects to the device, and lack of a different use for the device, find it obvious to vary/optimize the concentration of Helmus so as to provide the desired benefit, while subjecting the patient to the least amount of the agent possible, and that lowering the loose, ball-park figure of Helmus by 1 wt % would be obvious and within the level of ordinary skill in the art.

Conclusion

This is a RCE of applicant's earlier Application No. 09/063,227. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL**

even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt
August 28, 2003

BRIAN L. CASLER
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